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Mahwah, New Jersey, manufactures and markets medical implants such as artificial knee and hip implants. Starting in 1993, Howmedica filed a series of related patents that described processes for heating and irradiating polymers, namely, the ultra-high molecular weight polyethylene (UHMWPE) used in medical implants. The patents describe processes where a UHMWPE is first irradiated, which causes free radicals to form. The UHMWPE is then heated, which increases the oxidation resistance of the plastic by causing cross-links to form between free radicals produced by the UHMWPE's irradiation. A polymer with greater oxidation resistance retains its physical properties better, which makes it more suitable for use in medical implants because it deteriorates more slowly in the body.

Defendants are also corporations in the business of manufacturing and marketing medical implants. In February 2005, Howmedica brought this action against Defendants, alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to polymeric materials used in medical implants. These four patents are U.S. Patent No. 6,174,934 (filed Jan. 23, 1998); U.S. Patent No. 6,372,814 (filed June 28, 2000); U.S. Patent No. 6,664,308 (filed Jan. 8, 2002); U.S. Patent No. 6,818,020 (filed June 13, 2003) (collectively, "the patents-in-suit"). Howmedica claims that four of Defendants' products, Longevity, Prolong, Durusul, and XLPE, infringe these patents.

On July 21, 2006, Defendants filed their first joint motion for summary judgment on three of the four patents: the '934 patent, the '814 patent and the '308 patent. On April 23, 2007, the Court issued its Markman Order construing the claim terms and phrases needing construction as identified by the parties. On May 15, 2007, the parties argued the first motion for summary

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judgment. On June 13, 2007, the Court granted Defendants' joint motion for summary judgment on the issue of invalidity as to the '934 patent, the '814 patent and the '308 patent. The Court did not consider Defendants' motion for summary judgment on non-infringement on these three patents because this issue became moot.

On April 11, 2008, Defendants filed their third joint motion for partial summary judgment of non-infringement on claims 7, 10, 11, and 12 of the '020 patent (the "claims at issue"). The '020 patent is a continuation of application No. 10/041,118, now the '308 patent, which is a continuation of application No. 09/604,868, now the '814 patent, which is a continuation of application No. 09/012,345, now the '934 patent. All four patents share the same specification.

The claims at issue have the same claim limitation requiring that the claimed invention be "annealed at a temperature of greater than 25°C." ('020 Patent, col. 12.)

Table 1: Claims at Issue in Motion for Partial Summary Judgment

Claim No.	Claim Language
7	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and <u>annealed at temperature greater than 25°C.</u> for a sufficient time to have a solubility of less than 80.9% in trichlorobenzene and a non-increasing FTIR oxidation index during oven aging in air at 80°C. for up to 11 days.
10	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and <u>annealed at a temperature greater than 25°C.</u> for a sufficient time to have a level of free radicals of 1.0×10^{17} /gram or less and an oxidation index which does not increase during oven aging in air at 80°C. for 11 days.

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11	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and <u>annealed at a temperature greater than 25°C.</u> for a sufficient time to have a non-increasing FTIR oxidation index of 0.01 during oven aging in air at 80°C. for 11 days.
12	A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and <u>annealed at a temperature greater than 25°C.</u> for a sufficient time to have a non-increasing ETIR oxidation index of 0.01 or less during oven aging in air at 80°C. for 11 days and a solubility of less than 80.9% in trichlorobenzene.

(’020 Patent, col. 12 (emphasis added).) On April 23, 2007, the Court decided the Markman motions and construed the term “annealed at a temperature of greater than 25°C” to mean “annealed at a temperature greater than 25°C and less than the melting point of the material – approximately 140°C.” Howmedica Osteonics Corp. v. Zimmer, Inc., No. 05-897, 2007 WL 1231773, at *15 (D.N.J. Apr. 23, 2007) (“Markman Opinion”). Defendants move for summary judgment because their Accused Products are made by heating the UHMWPE above its melting temperature and, thus, do not fall within that limitation of the claims at issue.

STANDARD OF REVIEW

The same summary judgment standard applies to motions involving patent claims as it applies to motions involving other types of claims. See, e.g., Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 795-96 (Fed. Cir. 1990); Avia Group Int’l, Inc. v. L.A. Gear Calif., Inc., 853 F.2d 1557, 1560-61 (Fed. Cir. 1988). “[S]ummary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there

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is no genuine issue whether the accused device is encompassed by the claims.” Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999). The determination of patent infringement is a two-step process: “first, the scope of the claims are determined as a matter of law, and second, the properly construed claims are compared to the allegedly infringing device to determine, as a matter of fact, whether all of the limitations of at least one claim are present, either literally or by a substantial equivalent, in the accused device.” Teleflex, Inc. v. Ficoso N. Am. Corp., 299 F.3d 1313, 1323 (Fed. Cir. 2002); accord, e.g., CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1365 (Fed. Cir. 2002).

Only a genuine and material factual dispute between the parties will defeat a motion for summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A factual dispute is genuine if a reasonable jury could find for the non-moving party on that issue. It is material if, under the substantive law, that issue would affect the outcome of the suit. See id. at 248. At the summary judgment stage the court’s function is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. See id. at 249. In so doing, the court must construe the facts and inferences in the light most favorable to the non-moving party. Bartnicki v. Vopper, 200 F.3d 109, 114 (3d Cir. 1999).

DISCUSSION

Defendants state plainly that their “motion for summary judgment is limited to the narrow question of whether this single claim limitation [“annealed”] is present in Defendants[’] Accused Products, and does not address the presence or absence of any of the other limitations of those

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claims (e.g., solubility, free radical levels, and oxidation index).” (Defs.’ Reply Br. 2 (emphasis added).) In its Markman Opinion, the Court construed the term “annealed” and explained:

The language of the ’020 Patent claims is less clear because the context does not clarify the definition of the claims at issue. Also, the ’020 Patent claims differ from those of the other patents because they use the word “anneal” rather than “heat.” The Court will not base its interpretation of these claims on its construction of the ’934, ’814, and ’308 Patents, and will look to the specification to define the term “anneal” in the ’020 Patent claims. The ’020 Patent specification only describes an annealing process which takes place at a temperature between 25°C and 140°C. This confirms the Court’s understanding of the plain language definition of the term “anneal,” which is method of changing a material’s physical properties by heating a material to a point below its melting point and then cooling that material. The Court will interpret “annealed at a temperature of greater than 25°C” in claims 10, 11, and 12 of the ’020 Patent to mean exactly that: “annealed at a temperature of greater than 25°C” and less than the melting point of that material – approximately 140°C.

(Markman Opinion, at *15 (emphasis added).)

In opposing Defendants’ motion for partial summary judgment, Plaintiff does not dispute that Defendants’ Accused Products are made by heating the UHMWPE above its melting point.² Plaintiff and its expert witnesses, Dr. Lisa Pruitt and Dr. Stephen Li, admit to this fact. (Pruitt Infringement Report, Ex. 11 to Defendants’ Statement of Facts (“DSOF”), pp. 66, 106, 146, 186; Li XLPE Report, Ex. 14 to DSOF, p. 146; Li Durasul Report, Ex. 15 to DSOF, p. 104; Li

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Accused Product	Product Specification
XLPE	remelted above the melt temperature ($147^{\circ}\text{C} \pm 2^{\circ}\text{C}$)
Durasul	$150 \pm 10^{\circ}\text{C}$ until “100% melted material”
Longevity	post-irradiation heating at $150 \pm 5^{\circ}\text{C}$
Prolong	post-irradiation heating at $150 \pm 5^{\circ}\text{C}$

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Longevity Report, Ex. 16 to DSOF, p. 147; Li Prolong Report, Ex. 17 to DSOF, p. 143.)

During the August 12, 2008 hearing, Plaintiff conceded that under this Court's claim construction Defendants' Accused Products do not literally infringe the claims at issue. Rather, Plaintiff argues that Defendants' Accused Products infringe the claims at issue under the doctrine of equivalents.

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). The doctrine of equivalents functions to avoid placing the patentee "at the mercy of verbalism" and to avoid "subordinating substance to form." Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607-08 (1950). The Court and the parties agree that Warner-Jenkinson controls this Court's application of the doctrine of equivalents.

In Warner-Jenkinson, the Supreme Court reaffirmed the vitality of the doctrine of equivalents but clarified its scope. 520 U.S. at 21. Reviewing the Federal Circuit's divided en banc decision, where five of the twelve judges dissented, the Supreme Court explained the inherent conflict with that doctrine:

We do, however, share the concern of the dissenters below that the doctrine of equivalents, as it has come to be applied since Graver Tank, has taken on a life of its own, unbounded by the patent claims. There can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement.

Id. at 28-29. To ensure that courts do not go beyond the proper scope of the patent claims under

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the doctrine of equivalents, the Supreme Court set forth the following parameters:

Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety. So long as the doctrine of equivalents does not encroach beyond the limits just described, or beyond related limits . . . we are confident that the doctrine will not vitiate the central functions of the patent claims themselves.

Id. at 29 (emphasis added).

Here, the claim element “annealed” is material to defining the scope of the claims at issue.³ Because the Court had construed that term to mean “annealed at a temperature greater than 25°C and less than the melting point of the material—approximately 140°C” and all of the Accused Products are heated above the melting point, Plaintiff must identify a genuine issue of material fact as to how heating the UHMWPE below the melting point is equivalent to heating it above the melting point.

Plaintiff submits testimony from their expert witnesses on how “heating at or about 150°C is equivalent to annealing up to 140°C” under the “function, way, result” test. (Pl.s’ Opp. Br. 1 (emphasis added).) Dr. Stephen Li states:

In my opinion, heating irradiated UHMWPE to a temperature of about 150°C (140°C - 160°C), in accordance with the other patent claim terms performs substantially the same function in substantially the same way to obtain the same result as heating irradiated UHMWPE to a temperature greater than 25°C and less the melting point of that material – approximately 140°C.

³ During the August 12, 2008 hearing, Plaintiff indicated that it continues to disagree with the Court’s claim construction of the term “annealed.” As in its Markman brief, Plaintiff holds that there is no upper temperature limit to the definition of “anneal” and that the Court improperly included a claim limitation of “less than the melting point.”

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(Li Decl. ¶ 66 (emphasis added).) Dr. Lisa Pruitt states:

[E]ach claim element of the accused product must perform substantially the same function in substantially the same way to obtain the same result as the patent claim element.

(Pruitt Decl. ¶ 73 (emphasis added).) As evidence that Defendants' Accused Products "performs substantially the same function in substantially the same way to obtain substantially the same result,"⁴ Plaintiff's experts submit the following:

First, Defendants' Accused Products perform substantially the same function as the patent claims at issue. Plaintiff's experts state that one of ordinary skill in the art recognizes that post-irradiation heating UHMWPE in the manner described in the '020 patent will "improve the oxidation resistance of irradiated UHMWPE material through the cross-linking of free radicals."

(Li Decl. ¶ 70; Pruitt Decl. ¶ 76.) Plaintiff's experts describe the function of the limitation "annealed at a temperature greater than 25°C" as "[t]o improve the oxidation resistance of irradiated UHMWPE material through the cross-linking of free radicals and reducing free radicals". (Li Decl. ¶ 66; Pruitt Decl. ¶ 73.) Similarly, Defendants' Accused Products are annealed in a manner that will improve the oxidation resistance of irradiated UHMWPE material

⁴ The determination of patent infringement under the doctrine of equivalents requires:

a showing that the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method.

Aquatex Indus., Inc. v. Techniche Solutions, 479 F.3d 1320, 1326 (Fed. Cir. 2007) (the "function, way, result" test) (emphasis added).

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through the cross-linking of free radicals.⁵ Plaintiff's experts conclude that Defendant's post-irradiation heating at about 150°C performs substantially the same function as the "annealing" limitation. (Li Decl. ¶¶ 67-68; Pruitt Decl. ¶¶ 73-74.)

Second, Defendants' Accused Products are prepared substantially the same way as the patent claims at issue. Plaintiff's experts describe the way the "annealed at a temperature greater than 25°C" function is performed as by post-irradiation heating of the irradiated UHMWPE at a temperature above 25°C while out of contact with oxygen for a "sufficient time." (Li Decl. ¶ 66; Pruitt Decl. ¶ 73.) According to Drs. Li and Pruitt, "it doesn't matter if the irradiated UHMWPE material is heated at 50°C, 100°C, 145°C, 150°C, or 155°C as long as it is heated for a sufficient time" to have the properties claimed. (Li Decl. ¶ 72.) The way in which the irradiated UHMWPE of the Accused Products are heated "at a temperature above 25°C while out of contact with oxygen and, as literally limited by the Court, up to approximately 140°C for a 'sufficient time'" is by post-irradiation heating at temperatures ranging from about 140-160°C for about 5.5 to 23 hours. (Li Decl. ¶¶ 67, 69; Pruitt Decl. ¶ 74.) Heating the irradiated

⁵ Pl.s' Statement of Facts 209-231; Def. Exs. 9, 10 ("Irradiated/annealed bar stock shall meet the following mechanical and chemical/physical requirements: . . . Free Radical Levels by Electron Spin Resonance per Zimmer CRL 110298B: Undetectable."); Ex. C (Longevity is melt annealed which "virtually eliminates free radicals"); Ex. D at ZIM-39237, ZIM-39239 ("Heat material to allow the free radicals to recombine."); Ex. D at ZIM-39243 (Zimmer describes its accused Prolong cross-linked UHMWPE material/medical implants as having "improved oxidative resistance."); Ex. J at ZIM-35045 (Zimmer's Process Performance Qualification Confidential Summary Report for Electron Beam Cross-linking/Annealing of UHMWPE Bar states that "[t]he annealing cycle pass criteria was no detectable level of free radicals."); Ex. K at ZIM-36481 (Zimmer describes its accused Longevity cross-linked UHMWPE material/medical implants as "Not Susceptible [sic]" to oxidation.); Ex. E ("Smith & Nephew's XLPE] is fully annealed by heating above the melt temperature to minimize any potential for oxidation."); Ex. L ("No increase in oxidation level after accelerated aging compared to convention, non-irradiated UHMWPE as measured by FTIR"); Ex. H at ZIM-143652 ("the WIAM [Durasul] samples had almost no tendency to oxidize").

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UHMWPE of the Accused Products at a temperature of about 150°C is substantially the same way as heating irradiated UHMWPE at a temperature of less than 140°C as long as the irradiated UHMWPE is heated at 150°C for a sufficient time. (Li Decl. ¶¶ 64, 69, 71; Pruitt Decl. ¶ 71.)

Third, Defendants' Accused Products have substantially the same results as the patent claims at issue. Dr. Li describes the result of "anneal[ing] at a temperature greater than 25°C" as follows:

Result: Cross-links are created between free radicals and the level of free radicals is reduced, whereby the oxidation resistance of the irradiated UHMWPE material is improved. This is confirmed by the irradiated UHMWPE medical implant having a solubility of less than 80% in trichlorobenzene, a non-increasing FTIR oxidation index during oven aging in air at 80°C for up to 11 days, including, but not limited to, a non-increasing FTIR oxidation index of 0.01 or less, and a level of free radicals of 1.0×10^{17} spins/gram or less.

(Li Decl. ¶ 66.) Dr. Pruitt agrees, describing the result of "anneal[ing] at a temperature greater than 25°C" as:

irradiated UHMWPE with cross-linking between free radicals and a reduced level of free radicals in the irradiated UHMWPE material, thereby improving the oxidation resistance of the irradiated UHMWPE, which is reflected in the claimed properties, depending on the claim. This is confirmed by the irradiated UHMWPE material of the accused medical implants having a solubility of less than 80.9% in trichlorobenzene, a non-increasing FTIR oxidation index during oven aging in air at 80°C for up to 11 days, including, but not limited to, a non-increasing FTIR oxidation index of 0.01 or less, and/or a level of free radicals of 1.0×10^{17} spins/gram or less (depending on which properties or combination of properties are claimed).

(Pruitt Decl. ¶ 73.) Similarly, Defendants' Accused Products have substantially the same result of providing superior oxidation resistant medical implants with a reduced level of free radicals.

At the summary judgment stage, the Court is not questioning the credibility of Plaintiff's expert reports, only their relevancy. Plaintiff may be able to prove at trial that Defendants'

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Accused Products perform substantially the same function and achieve substantially the same result, which is that the resulting UHMWPE has certain properties of solubility, free radical levels and oxidation index. However, the Court rejects Plaintiff's same way analysis. Plaintiff attempts to shift the focus from the claim element "annealed" to the claim element "for a sufficient time" when its experts testify that "it doesn't matter if the irradiated UHMWPE material is heated at 50°C, 100°C, 145°C, 150°C, or 155°C as long as it is heated for a sufficient time" to have the properties claimed. (Li Decl. ¶ 72.) Plaintiff's position is tantamount to asking this Court to discard its claim construction in the Markman Opinion. Because Plaintiff's experts do not directly address how heating above the melting point is equivalent to heating below the melting point, their testimony that Defendants' Accused Products are made in substantially the same way as the claims at issue is irrelevant to this motion for summary judgment.

That Defendants' Accused Products are made by heating the UHMWPE above the melting point forecloses any argument that heating the UHMWPE below the melting point is equivalent, because a finding that opposites—below and above the melting temperature—are equivalent would vitiate the claim term "annealed." See Asyst Techs., Inc. v. Emtrak, Inc., 402 F.3d 1188, 1195 (Fed. Cir. 2005) (holding that "the district court was correct in ruling that the doctrine of equivalents cannot be extended to reach an 'unmounted' system . . . without vitiating the 'mounted on' limitation altogether"); SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1347 (Fed. Cir. 2001) ("Thus, if a patent states that the claimed device must be 'non-metallic,' the patentee cannot assert the patent against a metallic device on

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the ground that a metallic device is equivalent to a non-metallic device.”). Absolutely distilled, Plaintiff’s argument is: ignore the specific language and meaning of the claim element. Unmelt is the same as melt. An antonym is a synonym. Accordingly, the Court finds that there is no genuine issue of material fact regarding Plaintiff’s claim of patent infringement under the doctrine of equivalents.

CONCLUSION

The Court grants summary judgment of non-infringement in favor of Defendants on claims 7, 10, 11, and 12 of the ’020 Patent under literal infringement and under the doctrine of equivalents.

August 19, 2008

s/William H. Walls
United States Senior District Judge

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